

STATE OF COLORADO

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Dedicated to protecting and improving the health and environment of the people of Colorado

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Colorado Department
of Public Health
and Environment

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CDPHE laboratory implementing New HIV testing algorithm

To enable earlier diagnosis of HIV infection, and to provide rapid HIV testing results, the CDPHE laboratory will implement a new HIV testing algorithm beginning July 1, 2013. The new testing algorithm (see attached) follows the CDC/APHL HIV testing guidelines expected to be published soon. The new testing algorithm incorporates a 4th generation enzyme immunoassay (EIA) that detects HIV-1 p24 antigen and antibodies to HIV-1 and HIV-2, as well as a supplemental test that differentiates between HIV-1 and HIV-2. The 4th generation EIA has demonstrated a greater capability of detecting acute and primary HIV infection than previous EIAs and the HIV-1 Western blot. All serum and plasma specimens submitted to the CDPHE laboratory for HIV testing will be tested following the new testing algorithm.

Accompanying this letter, and also available on the CDPHE laboratory website (www.coloradostatelab.us), are specimen collection and submission instructions. ***Please note that specimen hold-times for the new testing algorithm have changed.*** Specimens that do not meet the hold-time criteria will be rejected. Please ensure that specimens are properly processed and stored to ensure specimen integrity and thus validity of testing results.

Please contact the CDPHE laboratory with questions and/or concerns regarding the new HIV testing algorithm.

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HIV Testing

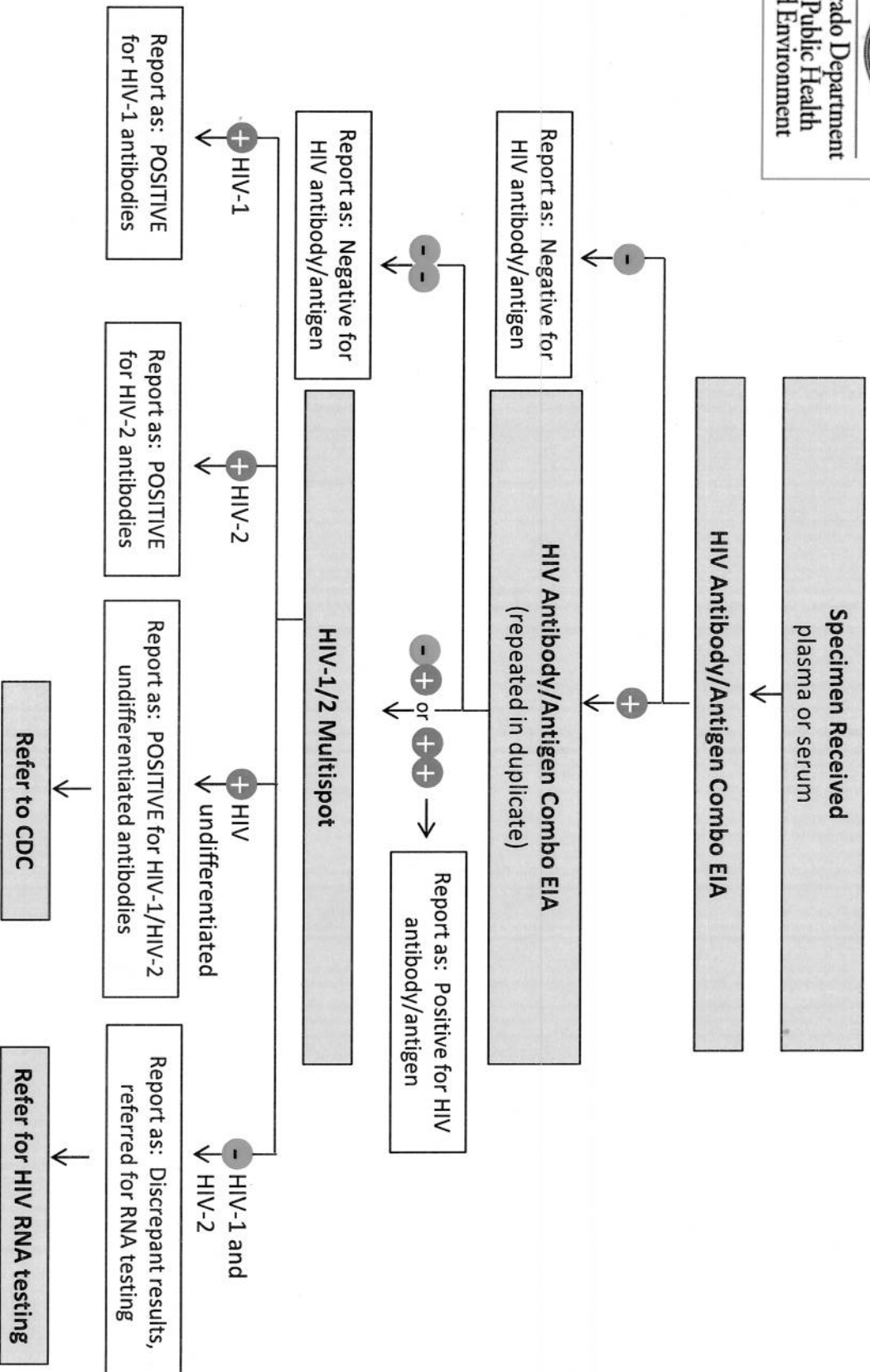
All specimens received by the CDPHE laboratory for HIV testing will be tested according to the CDPHE HIV testing algorithm

(www.coloradostatelab.us).

Test Method:	Enzyme immunoassay for the qualitative detection of HIV-1 p24 antigen and antibodies against HIV-1 and HIV-2.
Specimen Requirements:	A minimum of 1 mL of serum or plasma.
Specimen Storage:	<ul style="list-style-type: none"> • Whole blood: Room temperature ≤ 2 days from collection. • Serum or plasma separated from the clot: <ul style="list-style-type: none"> • Room temperature for ≤ 2 days from collection. • Refrigerated (2-8°C) for ≤ 7 days from collection • Frozen ($\leq -20^{\circ}\text{C}$) for ≤ 6 months from collection.
Specimen Transport:	<ul style="list-style-type: none"> • Whole blood: Room temperature if received by the lab ≤ 2 days from collection. • Serum or plasma separated from the clot: <ul style="list-style-type: none"> • Room temperature <u>if received by lab ≤ 2 days from collection.</u> • Refrigerated (2-8°C) <u>if received by lab ≤ 7 days from collection</u> • Frozen ($\leq -20^{\circ}\text{C}$) <u>if received ≤ 6 months from collection.</u>
Packaging and Shipping:	<ul style="list-style-type: none"> • Specimens must be properly labeled and a CDPHE requisition form completed with the specimen type and test indicated. Under "Test Order, Serology" check the box next to "HIV-1/HIV-2 EIA". • Place labeled specimen in a small biohazard specimen bag containing absorbent material & seal. • Place the laboratory request form in the pocket sleeve of the biohazard bag. • Place the specimen in an appropriate transport container <u>with refrigerant packs or dry ice as needed.</u> • <u>Indicate the transport and storage temperature on the outside of the transport container.</u> • Send via CDPHE courier service (www.coloradostatelab.us) or ship to: CDPHE Laboratory Services Division 8100 E Lowry Blvd Denver, CO 80230
Testing Schedule:	Testing is performed daily Monday-Friday. Results are reported within 72 hours of specimen receipt Monday-Friday.
Results Reporting:	<p>Upon completion of testing, all results are faxed or mailed to the submitter using the information provided on the requisition form.</p> <ul style="list-style-type: none"> • Negative for HIV-1 and HIV-2 • Positive for HIV-1 • Positive for HIV-2: • Positive for HIV-1/HIV-2 antibodies, undifferentiated • Discrepant results, referred for HIV-1 RNA testing • Negative for HIV-1 and HIV-2
Additional Information:	<ul style="list-style-type: none"> • For testing questions contact the Serology supervisor at 303-692-3094. • For additional information on courier service and to order test requisition forms and supplies go to www.coloradostatelab.us.



HIV Testing Algorithm





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HIV Testing Algorithm Interpretation

HIV Antibody/Antigen Combo EIA	HIV-1/2 Multispot	Supplemental Testing	Interpretation
Positive for HIV antibody/antigen	Positive for HIV-1 antibodies	Not performed	Positive for HIV-1
Positive for HIV antibody/antigen	Positive for HIV-2 antibodies	Not performed	Positive for HIV-2
Positive for HIV antibody/antigen	Positive for HIV-1/HIV-2 undifferentiated	Referred to CDC	Positive for HIV-1/HIV-2 Undifferentiated
Positive for HIV antibody/antigen	Negative for HIV-1/HIV-2 antibodies	HIV-1 RNA	Discrepant results, referred for RNA testing.
Negative for HIV antibody/antigen	Not performed	Not performed	Negative for HIV-1/HIV-2*

*If the patient meets the criteria for high-risk exposure, HIV-1 RNA testing is recommended.